IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LAURA COLICCHIO	:	
v.	:	Civil Action No. DKC 10-0015
OFFICE OF PERSONNEL MANAGEMENT	:	

MEMORANDUM OPINION

Presently pending in this action under the Federal Employees Health Benefits Act ("FEHBA") is a motion for summary judgment filed by Defendant Office of Personnel Management ("OPM"). (ECF No. 7). The issues are fully briefed and the court now rules pursuant to Local Rule 105.6, no hearing being deemed necessary. For the reasons that follow, OPM's motion will be granted.[1]

[1] The administrative record in this case was filed under seal because it contains medical records with personal information and identifiers. Redaction of the sensitive personal information would have rendered the record useless. The parties' memoranda, however, are not under seal and of necessity contain references to the sealed record. This opinion, too, will refer to portions of the sealed record, but all material has already been referenced by one or the other of the parties in an unsealed memorandum. This opinion will not be filed under seal, but the parties may request any redactions they feel should be made in the public record.

I. Background

The following facts are drawn from the administrative record before OPM.[2]

Plaintiff Laura Colicchio is a now 50-year-old woman who, for the past several years, has suffered from ankle problems. As the wife of a federal employee, Ms. Colicchio was covered by health insurance provided pursuant to the Federal Employees Health Benefits Program. During the time relevant here, Ms. Colicchio was insured through CareFirst BlueCross BlueShield ("CareFirst"), which provided coverage pursuant to a contract with OPM.

In May 2004, Ms. Colicchio suffered a fracture dislocation of her left ankle. (R. at 78).[3] After having multiple surgeries, including ankle hardware installation and removal, Ms. Colicchio continued to have trouble with her ankle. (R. at 78). On January 24, 2006, she presented to Dr. Justin Cashman with ankle pain that worsened on weight bearing. (R. at 78). After examining Ms. Colicchio and reviewing her most recent X-rays from July 2005, Dr. Cashman identified a "hypertrophic

[2] Because the court's review is based on only the administrative record, *Burgin v. OPM*, 120 F.3d 494, 497 (4th Cir. 1997), the facts do not draw from the affidavit Ms. Colicchio submitted with her opposition to summary judgment. (ECF No. 12-2).

[3] The administrative record is cited as "R. at page number."

fibular non-union with widening of the medial mortise, 15 degree malalignment to the ankle joint with destruction[,] and bone on bone arthritis of the entire lateral talar dome." (R. at 78). He diagnosed left ankle arthritis with valgus malalignment. (R. at 78). Dr. Cashman's notes reflect that he told Ms. Colicchio that he would not recommend any treatment for her ankle:

> I had a long discussion with the patient regarding treatment options. I do not think at the present time that the patient is a candidate for anything. If she is able to run three miles and only has occasional pain when she arises from a seated position I would personally leave this alone and no[t] do any surgery. However if she becomes very symptomatic and is unable to run those long distances I think with her malalignment, age, weight[,] and deformity, [she] would be best served with an ankle fusion. She is adamant against this. I do not think with her malalignment, age, and weight that she is a candidate for ankle replacement. She has asked about osteoarticular ankle replacements and in general I have not witnessed good results in either the literature or in my own experiences with these cadaver grafts.

(R. at 79). Although Dr. Cashman was obviously resistant to trying any "osteoarticular ankle replacement[]," he nevertheless referred Ms. Colicchio to Dr. Lew Schon for further discussion on the treatment approach. (R. at 79). Dr. Cashman suggested Dr. Schon because he felt the doctor "has had a good deal of experience on [ankle allografts] and is published on them." (R. at 79).

On February 6, 2006, Ms. Colicchio saw Dr. Gregory Guyton, one of Dr. Schon's colleagues at Greater Chesapeake Orthopedic Associates. (R. at 81). Dr. Guyton diagnosed avascular necrosis – bone death – to the left distal tibia, with ankle arthritis. (R. at 81). "[D]ue to the amount of arthritis and avascular necrosis," Dr. Guyton concurred with Dr. Cashman's recommendation that Ms. Colicchio receive a bone fusion and bone graft. (R. at 81). He added, "There are not too many more options." (R. at 81). In a follow-up visit to Dr. Cashman on February 16, Dr. Cashman told Ms. Colicchio that he "agre[ed] with Dr. Guyton's assessment." (R. at 80).

On August 30, 2006, Ms. Colicchio visited Dr. Schon for "a second opinion and other options other than an ankle fusion." (R. at 86). Dr. Schon's examination found some things about which to be optimistic: he noted no evidence of ankle instability, observed that she walked with a "normal gait," found good strength in the joint, and heard no popping or cracking when the joint was moved. (R. at 86). On review of her x-rays, however, he agreed that she exhibited "end stage osteoarthritis . . . and degenerative changes of her talar dome." (R. at 86). Despite these conditions, Dr. Schon recommended a cautious course of treatment:

> We discussed conservative and operative treatments. She is functioning quite well despite her severe radiographic

> osteoarthritis. I discussed her options including allograft surgery[4] and distraction arthroplasty. We discussed that with the allograft, she would have [an] approximately 50% success rate. . . . At this time, the patient will try to continue with anti-inflammatories and manage as best as she can.

(R. at 87).

Ms. Colicchio continued to experience pain, which led her to return to Dr. Schon on October 31, 2006. She informed Dr. Schon that, "given her current activities, her age, and even though she seems to understand the risks associated with the procedure and the success rate only being about 50%, she would like to proceed with allograft transplant." (R. at 84). Dr. Schon discussed the risks of the surgery with Ms. Colicchio and agreed to set it up. (R. at 84).

Ms. Colicchio then asked CareFirst to pre-certify coverage for the allograft procedure. On December 14, 2006, CareFirst notified Ms. Colicchio and Dr. Schon that it would not certify the procedure, as it was not determined to be "medically necessary." (R. at 7, 13). Under the terms of CareFirst's plan, procedures that are not medically necessary are excluded

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[4] In an ankle allograft, doctors graft joint surfaces harvested from a cadaver onto the patient's ankle joint. (*See* R. at 42-49).

from coverage. The relevant plan brochures define medically necessary procedures as those that are:

> 1. Appropriate to prevent, diagnose, or treat your condition, illness, or injury;
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> 2. Consistent with standards of good medical practice in the United States;
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> 3. Not primarily for the personal comfort or convenience of the patient, the family, or the provider;
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> 4. Not part of or associated with scholastic education or vocational training of the patient; and
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> 5. In the case of inpatient care, cannot be provided safely on an outpatient basis.

(R. at 154, 161).

CareFirst's letter explained that, after "medical director review,"[5] the company had determined that "there is little medical and scientific literature to support the device or treatment as standard therapy and [] the advantage of the total ankle replacement over the generally accepted surgical treatment has not been established." (R. at 7, 13).

Ms. Colicchio requested that CareFirst reconsider its decision by letter dated February 2, 2007. (R. at 15-16). In that letter, Ms. Colicchio emphasized (a) Dr. Schon's expertise and (b) the unfavorable outcomes likely to result from other

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[5] Records indicate that Dr. Linton Wray determined the procedure was not medically necessary. (R. at 26).

procedures. In response, ten days later CareFirst requested medical records and notes from Drs. Cashman, Guyton, and Schon. (R. at 17-19).[6] Among the items provided by Dr. Schon was a note dated February 21, 2007. R. at 85). That note explained that Ms. Colicchio's pain had worsened, her ankle had grown stiffer, and her adjacent joints were growing more dysfunctional. He opined that an ankle fusion would produce a high risk of increased stress on adjacent joints. And, perhaps most importantly, he concluded:

> Based on the advanced arthritis and progressive transfer stress with symptoms, she would be best served with a joint-sparing procedure such as the ankle allograft or ankle replacement, which can help preserve the ankle motion and in turn decrease the stress to her neighboring joints. The downside to ankle replacement, given her age, is the rate of early failure and the large bulk of bone graft that would subsequently need to be taken to salvage the failed replacement. With the allograft, less bone is taken.

Dr. Schon also provided CareFirst with medical literature discussing the allograft procedure. (R. at 16, 31, 117).

CareFirst referred the matter to an outside physician advisor, David West, D.O., on March 14, 2007. (R. at 24-25). After reviewing all the medical documentation presented and the

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[6] Ms. Colicchio certified that these doctors were the only individuals who treated her for her ankle condition in the prior two years. (R. at 20).

literature, Dr. West concluded that the ankle allograft procedure was "not consistent with standards of good medical practice in the United States . . . [as it] would be considered experimental and investigational and does not have sufficient literature backing its medical necessity in this situation of advanced osteoarthritis." Because of the "lack of scientific evidence and peer studies" supporting the procedure, Dr. West agreed that the procedure was not medically necessary and recommended upholding the denial of coverage. After this physician review, Ms. Colicchio's materials were sent to a medical director, Dr. Robert Thomas, for review and confirmation. (R. at 26-27). He also determined that the allograft procedure was "not standard" and recommended upholding the denial. (R. at 27).

By letter dated March 21, 2007, CareFirst informed Ms. Colicchio that its earlier denial would be upheld. (R. at 28-29). CareFirst again explained that the procedure was not "medically necessary" as that term was defined in the 2007 Federal Employee Health Benefit Plan Brochure. (R. at 28). It also emphasized that "[t]he fact that one of our covered providers has prescribed, recommended, or approved a service or supply does not, in itself, make it medically necessary or covered under this Plan." CareFirst sent a second letter the

next day upholding the denial of benefits for the inpatient hospital stay connected with the procedure. (R. at 30-31).

In an April 30, 2007 letter, Ms. Colicchio appealed CareFirst's decision to OPM. (R. at 32-34). The appeal letter was based on the assertion that: "[M]y present treating physician, Dr. Lew Schon, an orthopedic surgeon who specializes in disorders of the foot and ankle, has specifically recommended this surgery considering my condition." (R. at 32). She also argued that, among other things, CareFirst's decision was "arbitrary and capricious" because "BlueCross BlueShield has approved many of these exact same claims." (R. at 33).

In response to Ms. Colicchio's letter, OPM sought and obtained documentation from CareFirst on Ms. Colicchio's claim, including an "Explanation of Denial Report" that outlined CareFirst's findings. (R. at 70-74). OPM then commissioned its own medical review. (R. at 76-77). That medical consultant determined that the allograft was not medically necessary under the plan definition. (R. at 10). He explained:

> The gold standard procedure for this patient's condition is ankle fusion surgery. Allograft articular cartilage replacement is not likely to be effective in this case as the degenerative joint disease is too extensive by report of two different surgeons. There is no sufficient class I data and long term follow-up to support the efficacy of the allograft replacement procedure. Allograft and ankle arthroplasty remain investigational at this time.

Relying on the same rationale, OPM denied Ms. Colicchio's appeal on June 20, 2007. (R. at 165). According to the complaint, Ms. Colicchio proceeded with the surgery despite OPM's decision. (ECF No. 1 ¶ 13).

On January 5, 2010, Ms. Colicchio filed a complaint against OPM in this court under the FEHBA, 5 U.S.C. §§ 8901-14. (ECF No. 1). The complaint asserts that OPM's decision was "arbitrary, capricious, unsupported by the medical records in this case, and unsupported by any rational basis." (ECF No. 1 ¶ 17). Accordingly, it requests "monetary damages in the amount of $34,502.37 plus attorney's fees" or an alternative order "compelling OPM to reverse its 'final order.'" (*Id.* at 4).[7] OPM moved for summary judgment on May 6, 2010 (ECF No. 7); Ms. Colicchio opposed on June 8 (ECF No. 12). No reply was filed.

II. Standard of Review

A court reviews OPM actions under the FEHBA pursuant to the Administrative Procedures Act ("APA"), 5 U.S.C. § 706, based on

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[7] "Pursuant to 5 C.F.R. § 890.107(c), the only remedy available to individuals challenging an OPM decision denying benefits is "'a court order directing OPM to require the carrier to pay the amount of benefits in dispute.'" *Gordon*, 2010 WL 4449374, at *3 n.3. Accordingly, Ms. Colicchio cannot obtain a monetary judgment against OPM. *See Bryan v. OPM*, 165 F.3d 1315, 1319 (10th Cir. 1999) ("We read this language as a request for monetary judgment against Personnel Management – a remedy not contemplated by the government's waiver of sovereign immunity.").

the administrative record that was before the OPM when it made its determination. *Burgin v. OPM,* 120 F.3d 494, 497 (4th Cir. 1997); *see also Malek v. Leavitt*, 437 F.Supp.2d 517, 526 (D.Md. 2006). Under Section 706 of the APA, a court reviews an agency decision to determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In its analysis, the court must decide "whether the decision was based on a consideration of all the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Although the court's "inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Id.*

In a recent decision, this court explained how these general principles apply to an OPM review case "where the crux of the patient's challenge to OPM's decision was its determination as to whether certain treatment was medically necessary." *Gordon v. OPM*, No. DKC 08-3358, 2010 WL 4449374, at *4 (D.Md. Nov. 5, 2010). As noted in *Gordon*, there are two arguably conflicting approaches taken by the Fourth Circuit in reviewing OPM determinations. *Id.*; *see also Malek*, 437

F.Supp.2d at 526-27 (discussing possible conflict). In two cases, *Myers v. United States*, 767 F.2d 1072, 1074 (4th Cir. 1985), and *Caudill v. Blue Cross & Blue Shield of N.C.*, 999 F.2d 74, 79-80 (4th Cir. 1993), the Fourth Circuit applied a deferential standard of review, under which the OPM's decision would stand unless it was "plainly erroneous or inconsistent with the regulation." In *Burgin*, however, the Fourth Circuit undertook a *de novo* review of OPM's denial of coverage. 120 F.3d at 497-98. The court reasoned that, at least in that case, "the essential question [was] one of the interpretation of the contract's language, a question of law clearly within the competence of courts." *Id.* at 497-98.

While the Fourth Circuit has yet to reconcile these potentially divergent approaches, *de novo* review of an OPM decision on medical necessity is inappropriate. *Gordon*, 2010 WL 4449374, at *4 (citing *Campbell v. OPM*, 384 F.Supp.2d 951 (W.D.Va. 2004)). "OPM was entitled to considerable deference under these circumstances because OPM brings to the table substantial specialized knowledge regarding medical practice and procedure[,] making OPM especially well suited to make determinations regarding the necessity of medical procedures." *Id.* (quotation marks omitted). For the reasons articulated in *Gordon*, the deferential "plainly erroneous" or "arbitrary and capricious" standard should apply in this factually analogous

case – as both parties apparently agree. (ECF Nos. 7-1, at 15; 12-1, at 5).

III. Analysis

Ms. Colicchio provides two basic reasons why OPM's decision should be reversed: (1) the record does not support OPM's determination that an allograft procedure was not likely to be effective given Ms. Colicchio's condition; and (2) OPM overlooked literature supporting the usefulness of the allograft procedure. Keeping in mind that the court should not generally reevaluate the merits of Ms. Colicchio's claim or substitute its judgment for OPM's medical decisions, *Campbell*, 384 F.Supp.2d at 957-58, neither of Ms. Colicchio's assertions justifies reversal here. OPM based its decision on relevant factors, and "there is a rational connection between the facts found and the final decision that the treatment is not medically necessary." *Gates v. King*, No. 96-2710, 1997 WL 716426, at *2 (4th Cir. Nov. 18, 1997).

First, OPM's decision that the procedure was unlikely to be effective was rational and supported by the record. Two of Ms. Colicchio's treating physicians, Dr. Cashman and Dr. Guyton, seemed hesitant to recommend any allograft. Dr. Cashman felt Ms. Colicchio was not a candidate for ankle replacement – or

really "a candidate for anything."[8] He also expressed his concerns about "cadaver grafts." In addition, Dr. Guyton noted the "amount of arthritis and the avascular necrosis" and concluded that, beyond an ankle fusion, there were "not too many more options." Such conclusions reasonably support OPM's conclusion that Ms. Colicchio's condition was "too degenerative by report of two different surgeons." In addition to these treating physicians, the various medical reviews undertaken by CareFirst all supported OPM's decision. After reviewing Ms. Colicchio's medical records, the literature Dr. Schon provided, and other available information, those physicians also concluded that an allograft was not the best approach for her.

Second, OPM did not inappropriately overlook literature supporting the allograft procedure. The literature Ms. Colicchio cites was a part of the OPM administrative record. Although some of it could be read to support the use of the allograft procedure in Ms. Colicchio's case, OPM's medical reviewer cited his own literature, a February 2001 article from the *Journal of Bone and Joint Surgery*, to justify his finding

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[8] Ms. Colicchio points out that Dr. Cashman, in a February 16, 2006 note, concluded that she was a candidate for ankle replacement. (R. at 80). The note, which was dictated but not read by Dr. Cashman, stated at the beginning that he agreed with Dr. Guyton's assessment, who he understood concluded that Ms. Colicchio was "not a candidate for ankle replacement."

that the efficacy of the allograft procedure had not yet been shown. Moreover, as OPM notes, other literature in the record – including the literature Dr. Schon submitted - also supports its conclusion. (*See, e.g.*, R. at 39 (reproduced from Tontz, et al., *Use of Allografts in the Management of Ankle Arthritis*, 8 Foot & Ankle Clinics of N. Am. 361, 361 (2003)) ("[A]rthrodesis currently is considered the gold-standard for end-stage arthrosis of the tibiotalar joint."); R. at 52 (reproduced from (Kim., et al., 23 *Treatment of Post-Traumatic Ankle Arthrosis with Bipolar Tibiotalar Osteochondral Shell Allografts*, Foot & Ankle Int'l 1091, 1091 (2002)) ("Surgical treatment typically relies on arthrodesis or prosthetic arthroplasty."); R. at 60 (reproduced from Kim, *supra*, at 1099) ("Traditionally, post-traumatic arthrosis has been treated by tibiotalar arthrodesis, which provides a satisfactory outcome in the majority of patients."); R. at 63 (reproduced from Kim, *supra*, at 1102) ("We continue to offer fresh osteochondral shell allografts as an *alternative treatment* for post-traumatic ankle arthropathy to selected patients who refuse ankle arthrodesis." (emphasis added))). Indeed, one of the studies Ms. Colicchio now heavily relies upon candidly concedes the lack of clinical data on the use of ankle allografts:

> Although multiple studies have demonstrated the success of osteochondral allografts for the treatment of osteochondral defects of

> the knee, there are few reports that document the results of allografts performed for talar lesions. . . . Early results are encouraging, but studies evaluating this procedure are limited.

(R. at 36-37 (reproduced from Tasto, et al., *The Diagnosis and Management of Osteochondral Lesions of the Talus: Osteochondral Allograft Update*, 19 Arthroscopy: J. of Arthroscopic & Related Surgery 138, 139-40 (2003)). In sum, OPM's decision appropriately accounted for the medical literature.

The common chord of Ms. Colicchio's arguments is a straightforward contention: Dr. Schon indicated the procedure was necessary; consequently, it should be deemed necessary. Such an argument places too much weight on the opinion of one (admittedly skilled) physician. "The fact that [Ms. Colicchio] has presented reports from other doctors who disagree with [OPM] is not sufficient for this court to conclude that OPM's decision was arbitrary and capricious." *Gordon*, 2010 WL 4449374, at *5. Perhaps it would have been inappropriate to reject Dr. Schon's opinion out of hand, but that is not what OPM did here. Instead, it relied on an independent medical reviewer whose opinions aligned with several other doctors. Those opinions entitled OPM to disagree with Dr. Schon. As another court explained in a different context:

> [A] *diagnosis* provided by a treating physician is likely to be more reliable than one provided by a reviewing physician. In

> contrast, however, the process of reviewing a claim for benefits does not rely on the nuances that can be observed through personal examination of the participant. Rather, it is confined to the process of applying a standardized and narrowly defined list of qualifying criteria to the participant's particular set of symptoms, as documented by treating physicians in the participant's medical records, to determine whether a participant qualifies for coverage for certain type of treatment under the Plan. Such a mechanical process would seem to be no more or less reliable when conducted by a reviewing physician than when conducted by a treating physician.
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> Blue Cross cannot arbitrarily discredit the contrary opinion of Patricia's treating physicians, but neither must Blue Cross give any special weight to a treating physician's opinion, or even explain why his opinion was not given as much weight as that of the reviewing physicians. As such, the existence of five separate medical opinions supporting Blue Cross's decision substantially justifies Blue Cross's denial of benefits, and the contrary conclusions drawn by Patricia's treating psychologists at Second Nature and Island View are not enough to render the decision irrational.

Jon N. v. Blue Cross Blue Shield of Mass., 684 F.Supp.2d 190, 203-04 (D.Mass. 2010); *accord Campbell*, 384 F.Supp.2d at 957 ("It is precisely such clinical evidence, rather than the anecdotal evidence provided by Campbell's doctors, that is relevant in determining medical necessity.").[9]

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[9] Moreover, as in *Campbell*, there is some suggestion that Ms. Colicchio proposed the idea of an allograft herself. She first raised the issue with Dr. Cashman and then went to Dr.

Because OPM considered relevant facts and made a determination reasonably supported by the record, it cannot be said that its decision was arbitrary, capricious, or plainly erroneous.

IV. Conclusion

For the foregoing reasons, Defendant's motion for summary judgment will be granted. A separate order will follow.

/s/
DEBORAH K. CHASANOW
United States District Judge

Schon to discuss options other than an ankle fusion. Despite his August 2006 recommendation to "possibly live with" her condition, she informed Dr. Schon that "she would like to proceed with the allograft" in October 2006. Dr. Schon's full endorsement of the procedure appears in only February 2007, after Ms. Colicchio elected to have the surgery. The fact that her doctors did not propose an ankle allograft "of their own accord . . . does not inspire much confidence in her claim of 'medical necessity.'" *Campbell*, 384 F.Supp.2d at 957.